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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF

ODILE AUBRUN-SONNEVILLE, ET AL. : EXAMINER: VENKAT, J.A.

SERIAL NO: 10/813,013 FILED: MARCH 31, 2004

· GROUP ART UNIT: 1615

FOR: COMPOSITION CONTAINING AN :

AMPHIPHILIC POLYMER, USES

THEREOF

DECLARATION UNDER 37 C.F.R. § 1.132

COMMISSIONER FOR PATENTS ALEXANDRIA, VIRGINIA 22313

Sir:

SIR:

- I, Florence l'Alloret, state that:
- 1. I am a graduate of <u>Natural Target</u> and received a <u>p&D</u> degree in the year RTis 6
- - 3. I am an inventor of this application.
- I understand the English language or, at least, that the contents of the Declaration were made clear to me prior to executing the same.
 - 5. The following experiment was carried out under my direct supervision and control.
- 6. I understand that the claims of this application are to a composition in the form of an oil-in-water emulsion with an oily phase dispersed in an aqueous phase, at least one lipophilic emulsifier, and at least one amphiphilic polymer specifically defined in the claims.

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 I also understand that the U.S. patent office has rejected the claims in view of U.S. patent no. 6.645,476.

8. I am familiar with this patent as it is referenced in the above-referenced application on page 3 in relation to its European counterpart.

9. This '476 patent described preferred water-soluble polymers (col. 3, lines 23-67) including AMPS and fatty alcohol polyglycol ethers (e.g., Genapol® LA-070). However, on page 4 of the above-referenced application, it is stated that "the polymers illustrated in the said document do not produce O/W emulsions with cosmetic properties that are very pleasant for the user while at the same time being very stable and easy to produce." Comparative Examples 1 and 3 in the above-referenced application shows that emulsions containing the polymer as the only emulsifier were not stable.

10. The '476 patent describes oil-in-water emulsions in Examples 41-43 while the other examples are water-in-oil or water-based compositions. Example 41 includes a hydrophilic co-emulsifier (sodium cocyl glumate) and Eamples 42 and 43 contain no co-emulsifiers.

 I understand that the '476 patent suggests the possibility of emulsions (including oil-in-water, col. 9, lines 11-15) and the inclusion of coemulsifiers, such as sorbitan esters and others (see col. 9, lines 27-63).

12. None of the Examples provided in the '476 patent include a lipophilic emulsifier and the mere suggestion to include a coemulsifier in col. 9, lines 27-63 fails to illustrate the importance of a <u>lipophilic</u> emulsifier as opposed to another type of emulsifier, particularly considering the rather long and general list of other surfactants, which themselves can act as emulsifiers in certain instances)

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- 13. The above-referenced application provides comparative data demonstrating the importance of including a lipophilic emulsifier (see comparative Examples 1 and 3) but not other types of emulsifiers (see comparative Example 2).
- 14. Even in view of what is described in the '476 patent and what I know about this field, I would not have expected that a lipophilic emulsifier (further examples follow) resulted in such a dramatic difference compared to other emulsifiers.
- 15. The following tests provide two additional examples of a silicone surfactant and a sucrose ester, which are two additional examples of a lipophilic emulsifier as provided in the above-referenced application.

	Example A according to the invention	Example B according to the invention
Oily phase:		
Cyclohexadimethylsiloxane	6	6
Parleam® oil	9	9
sucrose tristearate (RYOTO SUGAR ESTER S 370 from Mitsubishi)	0.5	-
PEG/PPG 18/18 dimethicone (DOW CORNING 5225C FORMULATION AID)	•	0.5
Aqueous phase		
Copolymer of AMPS and of Genapol LA-070 methacrylate (with 8.5 mol% of monomer of formula II)	ı	1
Triethanolamine as an aqueous 10% solution	0.06	0.06
Preserving agents	1	1
Water	qsp 100%	qsp 100%
pH	6.65	6.51
Viscosity	107.5 cPoises	188 cPoises

- 16. The compositions obtained are in the form of fine and stable emulsions (fluid milk), the viscosity of each composition being measured using a Rheomat 180 machine at 25°C at a shear rate of 200 s⁻¹ using a No. 2 spindle.
- 17. While only a few examples of a composition of the invention are provided that demonstrate why a lipophilic emulsifier was so much better than other emulsifiers, the examples provided in the application along with those presented here demonstrate a trend

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from which I can conclude that similar stable compositions would result based on the combination as described in the application.

18. The undersigned declares further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Signature

Florence ('Alloret

Date

23.01.03